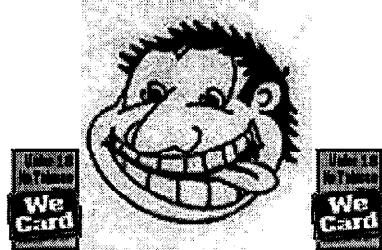




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(1)Unit of 20 packs of Cinnamon Flavor Gum. Must be 18/or of legal smoking age to purchase. Helps fight nicotine cravings and helps you quit!

Price \$12.99

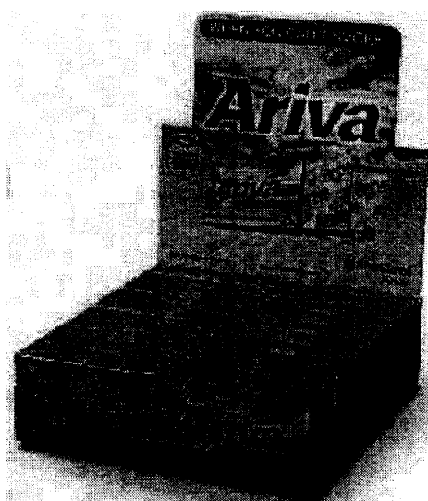
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Ariva (Compressed Powdered Tobacco in Tablet Form)



Ariva is an innovative smokeless tobacco product that neither requires smoke to be taken into the lungs nor expose others to second-hand smoke. It is a compressed powdered tobacco bit, or cigarette piece, designed to be dissolved in the mouth. It offered adult cigarette smokers an acceptable alternative when they cannot, or do not want to smoke. Perfect for parents who don't want to expose their children to secondhand smoke, travelers on plane trips, or restaurant patrons who are prohibited from smoking in dining rooms. Unlike cigarettes, Ariva does not contain the hundreds of toxic chemical constituents found in tobacco smoke. Additionally, the tobacco used in Ariva cigarette pieces is 100 percent Virginia StarCured tobacco.

Q:Is Ariva a cessation product?

A: Ariva is not a cessation product. Cessation products are marketed to help people stop smoking. Ariva is a smokeless tobacco product that was developed to give smokers who find themselves in smoke-free settings, such as office buildings or airplanes, an alternative to cigarettes.

Q: What is special about Ariva?

A: It is hard-snuff tobacco, and therefore it does not require the user to spit. For this reason, it may be more aesthetically appealing as an alternative to cigarettes than traditional moist snuff products.

Q: Will Ariva be widely available?

A: Ariva will be marketed and sold ONLY to adult tobacco users. Like other tobacco products, Ariva will be available only to consumers who

can show valid proof of age.

Q: Does Ariva contain nicotine?

A: All tobacco products, including Ariva contain nicotine, an addictive substance. For this reason, quitting tobacco use or not starting is the best option.

NOT FOR SALE TO MINORS. 20 cigarett pieces

for \$9.99. More expensive than cigarettes but worth it! Get the nicotine you crave when you are in a situation where you cannot smoke!

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Top : ** SMOKELESS TOBACCO **

Ariva



Product Details

Stock #: Ariva

Price: \$ 5.00

WHEN YOU CANT
SMOKE TRY ARIVA!
ARIVA IS AN
INNOVATIVE SMOKELESS
TOBACCO PRODUCT
THAT NEITHER REQUIRES
SMOKE TO BE TAKEN
INTO THE LUNGS NOR
EXPOSE OTHERS TO
SECONDHAND SMOKE.

IT IS A COMPRESSED,
POWDERED TOBACCO
BIT, OR CIGARETT PIECE,
DESIGNED TO BE
DISSOLVED IN THE
MOUTH. IT OFFERS
ADULT CIGARETTE
SMOKERS AN
ACCEPTABLE
ALTERNATIVE WHEN
THEY CANNOT, OR DO
NOT WANT TO SMOKE.

VERY SIMILAR IN
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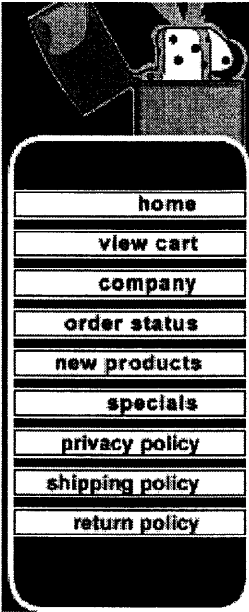
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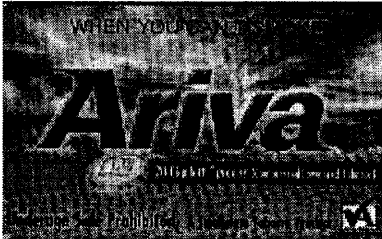
shipping policy

return policy



Top : [HOT DEALS - LIMITED OFFERS](#)

ARIVA - WHEN YOU CANT SMOKE!



Product Details

Stock #: ariva

WHEN YOU CANT
SMOKE TRY ARIVA!
ARIVA IS AN INNOVATIVE
SMOKELESS TOBACCO
PRODUCT THAT NEITHER
REQUIRES SMOKE TO BE
TAKEN INTO THE LUNGS
NOR EXPOSE OTHERS TO
SECONDHAND SMOKE. IT
IS A COMPRESSED,
POWDERED TOBACCO BIT,
OR CIGARETT PIECE,
DESIGNED TO BE
DISSOLVED IN THE
MOUTH. IT OFFERS ADULT
CIGARETTE SMOKERS AN
ACCEPTABLE
ALTERNATIVE WHEN
THEY CANNOT, OR DO NOT
WANT TO SMOKE. VERY
SIMILAR IN TASTE TO AN
ALTOLD MINT.

Price: \$6.95
Special: \$5.00

Qty:

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TYPE:



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Featured Products

ARIVA



PRODUCT DESCRIPTION

Ariva is an innovative smokeless tobacco product that neither requires smoke to be taken into the lungs nor expose others to secondhand smoke. It is a compressed, powdered tobacco bit, or cigarette piece, designed to be dissolved in the mouth. It offers adult cigarette smokers an acceptable alternative when they cannot, or do not want to smoke.

ARIVA CONSUMERS

According to market research, 40 percent of America's 47 million smokers are looking for acceptable alternatives to cigarettes. Ariva is for adult smokers who increasingly find themselves in situations where they cannot or choose not to smoke - for example, parents who don't want to expose their children to secondhand smoke, travelers on plane trips, or restaurant patrons who are prohibited from smoking in dining rooms.

ARIVA CONTENTS

Unlike cigarettes, Ariva does not contain the hundreds of toxic chemical constituents found in tobacco smoke. Additionally, the tobacco used in Ariva cigarette pieces is 100 percent Virginia StarCured tobacco.

PACKAGING AND LABELING

The Ariva package features a warning that states, "There are no safe tobacco products. Quitting or not starting is your best option." It is Star Scientific's stated view that consumers should be encouraged not to use any tobacco products. The package also states prominently that Ariva is for adults only, and is not for sale to minors, which underscores Star's position that all efforts should be made to keep tobacco products out of the hands of minors.

Ariva is the first tobacco product to use child- resistant packaging: the cigarette pieces are sold in blister packs. The company made this decision in part after reviewing poison control data on the annual incidence of illness arising from toddlers' accidental ingestion of whole cigarettes or cigarette butts.

For more information about Ariva contact us at 1- 866-GOARIVA or log on to www.goariva.com

ARIVA QUESTIONS

Q. Is ARIVA a cessation product?

A. Ariva is not a cessation product. Cessation products are marketed to help people stop smoking. Ariva is a smokeless tobacco product that was developed to give smokers who find themselves in smoke- free settings, such as office buildings or airplanes, an alternative to cigarettes.

Q. What is special about ARIVA?

A. It is hard-snuff tobacco, and therefore it does not require the user to spit. For this reason, it may be more aesthetically appealing as an alternative to cigarettes than traditional moist snuff products.

Q. Will ARIVA be widely available?

A. Ariva will be marketed and sold ONLY to adult tobacco users. Like other tobacco products, Ariva will be available only to consumers who can show valid proof of age.

Q. Does ARIVA TI contain nicotine?

A. All tobacco products, including Ariva, contain nicotine, an addictive substance. For this reason, quitting tobacco use or not starting is the best option. This is Star's position, and it is stated on the Ariva TI packaging, as well as on the packaging of our other smokeless products.

Q. What is Star Scientific?

A. Star Scientific is a technology- oriented tobacco company whose primary purpose is to develop the technology and tobacco products that can lessen the harm linked with tobacco. Star Scientific believes that all available technologies should be employed to develop products that can reduce the harm associated with long term smoking.



JUL 22 1998

Paul L. Perito
Paul, Hastings, Janofsky & Walker LLP
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Mr. Perito:

This responds to your letter of December 22, 1997, to Robert Lake of the Center for Food Safety and Applied Nutrition, regarding your client's proposed product, **GUMSMOKE** chewing gum. We would also like to thank you for your commitment to work closely with the Food and Drug Administration (FDA) prior to marketing this product and for providing valuable information and materials, including a label mock-up and promotional labeling, to assist us in evaluating the product. We have also included in our review two press releases dated October 15, 1997, and February 17, 1998, issued by your client, Star Tobacco & Pharmaceuticals, Inc. ("Star Tobacco"), the prospective manufacturer and marketer of this product.

We have a number of concerns about the proposed marketing of this product from a regulatory and public health perspective. According to the information you supplied to the agency, Star Tobacco is considering marketing **GUMSMOKE**, a tobacco-flavored chewing gum, as a confection. Although the product is said to contain no tobacco or nicotine, we are very concerned that the name, label, and promotional materials associated with the product may create the perception that **GUMSMOKE** is a milder, safer form of smokeless tobacco or a milder, safer substitute for smoking conventional cigarettes. Alternatively, tobacco users may perceive **GUMSMOKE** as a safer, inexpensive substitute for FDA-approved smoking cessation products, especially the over-the-counter drug product **NICORETTE** (nicotine polacrilex gum).

Several aspects of **GUMSMOKE**, as that product was presented in your materials, are contributing to our concern, including:

- the similarity of the name **GUMSMOKE** to **GUNSMOKE**, the latter of which is a conventional tobacco/nicotine-containing cigarette product currently marketed by Star Tobacco;
- **GUMSMOKE**'s chewing gum form and the proposed labeling statement "Underage Sale Prohibited," which when combined with other representations, may suggest that this product is similar to, or the same as, smokeless tobacco and/or **NICORETTE** gum; and

- your client's name, "Star Tobacco & Pharmaceuticals," the name GUMSMOKE, and statements such as "GUM FOR SMOKERS," "WHEN YOU CAN'T SMOKE," "THE SMOKE THAT HAS NO MATCH," "THE ALTERNATIVE YOU NEED," and "Underage Sale Prohibited" appearing on the labeling, all of which may suggest that GUMSMOKE provides the same psychopharmacological effects as smokeless tobacco, conventional cigarettes, or nicotine-containing, smoking cessation drug products.

Furthermore, given your client's stated commitment to reducing the health risks associated with the use of tobacco products, we expect that you would share our concern that GUMSMOKE not appeal to children. The tobacco flavor of GUMSMOKE may help children and teenagers become accustomed to the taste of tobacco while chewing gum. This concern can in no way be allayed by labeling the product as not for sale to minors in light of the difficulty retailers will experience in preventing the sale of this gum product to minors. We also disagree with the proposed labeling statement "Underage Sale Prohibited." We note that, except for tobacco products and certain approved drug products, which are required to bear labeling restricting their sale to adults only, the sale of chewing gum products that legally qualify as "food" are not so restricted.

Aside from the materials provided with your letter, your client's "NEWS RELEASE" of October 15, 1997, is cause for concern. That release describes GUMSMOKE as containing tobacco leaf that has undergone a process to preserve its nicotine content while eliminating the presence of tobacco-specific nitrosamines. The release also states that an investigational new drug application (IND) for a product named GUMSMOKE has been filed with FDA to substantiate its effectiveness when used for smoking cessation. On the other hand, your letter to Mr. Lake proposes a different product under the name GUMSMOKE, one without this tobacco component and without any of the express smoking cessation claims that appear on several FDA-approved drug products. The conflicts between the product as described in the release and the product as described in your letter are of concern to the agency because of the potential for causing consumer confusion, especially in light of the coverage given to the release, including stories reported by The Associated Press, CNN, and USA TODAY.

Your client's February press release, which followed your letter to Mr. Lake, adds yet more confusion about the formulation and intended use of GUMSMOKE. That release identifies GUMSMOKE as a "specially formulated" product. However, except for describing this version as "nicotine free," the release does not adequately differentiate GUMSMOKE from the specially processed "TSNA-free" tobacco-containing products being developed by your client. Additionally, this press release may be interpreted as characterizing GUMSMOKE as a safe and

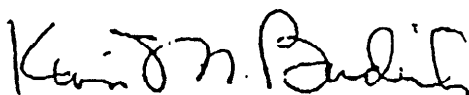
effective product for "...people who want to quit smoking...." Smoking cessation claims such as these, and any representations that the use of this product as an alternative to tobacco may prevent or mitigate diseases associated with tobacco use, would be regarded by the agency as "drug" claims under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), and any such representations would cause this product to be a "new drug" within the meaning of section 201(p) of the Act.

We have taken note of Star Tobacco's stated desire to produce a range of products beneficial to tobacco users. In light of this, we are also concerned, as a public health matter, that the use of GUMSMOKE may delay a successful attempt at smoking cessation with the use of drug products approved by FDA on the basis of scientific evidence demonstrating effectiveness for cessation. This concern arises from the positioning of this product in the market place through its labeling and its chewing gum form, as noted above, and from the substantially less expensive nature of GUMSMOKE when compared to the approved products.

In consideration of your client's intention to remain in full compliance with the letter and spirit of the law and all pertinent regulations, we would like you to address these concerns before you proceed further with your marketing plans. We also wish to note that we have additional concerns about the press releases issued by your client and these concerns will be addressed separately.

If you have any questions concerning the content of this letter, you may contact this office at (301) 594-1065.

Sincerely yours,



Kevin M. Budich
Compliance Officer
OTC Compliance Team (HFD-312)
Division of Drug Labeling and
Nonprescription Drug Compliance
Office of Compliance
Center for Drug Evaluation and Research

Underage Sale
Prohibited
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GUM SMOKE
WHEN YOU CAN'T SMOKE

5 STICKS
GUM FOR
SMOKERS

For more information, see Tobacco & Cigarette Tax 168, Volume 1, Page 10, 10/10/01

GUM SMOKE
WHEN YOU CAN'T SMOKE

5 STICKS
GUM FOR
SMOKERS

For Distribution

4284

THE SMOKE THAT HAS NO MATCH

NEW!

UNDERAGE
SALE
PROHIBITED

GUM SMOKE
WHEN YOU CAN'T SMOKE

5 STICKS
GUM FOR
SMOKERS

THE ALTERNATIVE YOU NEED

It's the perfect alternative for a smoke-free environment. Higher margins than cigarettes. Put it in your store and watch your sales light up. Contact your distributor or call 1-800-763-4480.

Star Tobacco & Pharmaceuticals, 16 S. Market St., Petersburg, Virginia, 23803

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Gallahan

UNSMOKETM
WHEN YOU CAN'T SMOKE

GUM FOR



MADE OF: sugar, chewing gum base, corn syrup, dextrose, sorbitol, natural and artificial flavors, titanium dioxide, BHT (to maintain freshness). Made in Mexico.

For nutritional information write: Star Tobacco & Pharmaceuticals 16 S. Market St. Petersburg, Virginia 23803

UNSMOKETM
WHEN YOU CAN'T SMOKE

